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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/582,342 | 09/18/2000 | Rudi Brands | 01975.0025 | 8325 |

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| EXAMINER | |
|---|---|
| LI, BAO Q | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1648 | 23 |

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/582,342 | Applicant(s) BRANDS, RUDI | |
|---|---|---|---|
| | Examiner Bao Qun Li | Art Unit 1648 | |

*-- The MAILING DATE of this communication appears on the cov r sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *20 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,2 and 7-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2 and 7-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 22.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

Claims 1, 2 and 7-26 are pending.

### *Response to Amendment*

IDS filed in 01/06/2003 has been noticed. This is a response to the amendment, paper No. , filed 06/23/01. Claims 1, 2, and 22 have been amended. Claims 1-2 and 7-2 are pending before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### *Claim Rejections - 35 USC § 103*

Claims 1-2 and 7-26 are still rejected under 35 U.S.C. 103(a) as being unpatentable over Griffiths et al. (Scale-up of suspension and Anchorage-dependent Animal cells in Basic Cell Culture Protocols, Edited by Pollard et al. Humana Press Inc., 1997, pp.59-75), and Pollard (Basic Cell Culture Protocols, Edited by Pollard et al. Humana Press Inc., 1997, Step 14-20 on page 3 and Section 3.2 on page 4-5) on the same ground as stated in the previous Office Action.

Applicant traverse the rejection and submit that the references cited against the claimed invention may not belong to the prior art to the present Application because the cited reference did not appear on the shelves of the library of Des Moines University until January 14, 1999, which is long after Applicant's priority date (December 24, 1997). Applicant further point that unless the examiner can show an earlier publication date, wherein the publication date according to the M.P.E.P. that " A publication dissemination by mail is not prior art until it is received by at least one member of the public....".

Applicant's argument has been considered, however, it is not persuasive because the cited references of Griffiths et al. and Pollard received by one member of a public by August 27, 1997 (see the notice from The scientific Library of Nation Cancer Institute – Frederick Cancer Research Dependent Center, NCI-FCRDC).

Nevertheless, Applicant is reminded that according to 35 U.S.C. 102 that form the basis for the prior art rejections is as follow:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

In the instant case, the cited references were all published before the filing date of the Application, therefore, they are all prior art.

Applicant further argue that the combination of cited reference does not teach all limitation of the claimed invention and the logical of the rejection by the previous Office Action, which views the claimed invention as a modification of splitting cells in different rations rest on a mistaken premise.

Applicant's argument has been respectfully considered; however, it is not fond persuasive because the cited reference of Griffiths et al. and Pollard teach all aspects of scale-up culturing suspension and anchorage dependent cell culture, unless the exactly split the preproduction of cell population into two parts, which is noticed by Office as a modification of splitting cells in different rations.

Applicant on one hand, argues that Applicant's cell are not merely divided in different split ratios that falls within the range of ratios disclosed in the cited document. On the other hand, Applicant asserted that the applicant's sole of claimed invention as cited in claim 1 as dividing the cells of prepaduction batch into two separate parts and this division is not taught or suggested in the cited documents, regardless any split ratio, which may be disclosed.

Applicant's argument has been respectfully considered; however, it is not found persuasive because the sole of the claimed invention is to divide culturing cells into two parts. Compared with dividing culturing cell into more than tow parts, it is a modification of splitting cells in different ratios. As it is well known in the art that the time required for reaching the optimal condition of cells growth in the same culture medium dependent on the cell density. In other word, if the cell density is too low when you split them, it require longer time to grow to an optimal condition for the consequential utilization, whereas, if the cell density is higher when you split them, it required short time to grow to an optimal condition for the consequential utilization. Therefore, it is proper to considering that the claimed invention is regarded as a modification of the splitting cells in different ratios, which is generally recognized as being within the level of the ordinary skill in the art, In re Rose, 105 USPQ 237 (CCPA 1995). Because

other general conditions for large scale-up culturing both suspension and acchorage-depedent animal cells has bee explicitly disclosed in the cited prior art of Griffiths et al. and Pollard, (Scale-up of suspension and Anchorage-dependent Animal cells in Basic Cell Culture Protocols, Edited by Pollard et al. Humana Press Inc., 1997, pp.59-75), the discovering the workable ranges as 1 to 1 or 1 to 2 splitting cells in culture involves only routine skill in the art, In re Aller, 105, USPQ 233. Unless there is unexpected result by dividing the culturing cells into two parts compared with dividing cells into three part five parts, the rejection is maintained since the claimed invention as a whole is prima facie obvious absence unexpected results

***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 8:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li February 24, 2003

JAMES HOUSEL 3/10/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600